

REMARKS

The above amendments and these remarks are responsive to the Office action dated October 19, 2005. Claims 1-13 are pending in the application. In the Office action claim 6 was rejected under 35 U.S.C. § 112, second paragraph, claims 8, 10, 11, and 13 were rejected under 35 USC §103(a), claims 1-4, 8-11, and 13 were rejected under the judicially created doctrine of obviousness-type double patenting, claim 5 and 12 were objected to, and claim 7 was found to be allowable. By way of the present amendment, claims 6 and 13 are amended. In view of the amendments above, and the remarks below, Applicants respectfully request reconsideration of the rejected claims under 37 C.F.R. § 1.111.

Rejections under 35 U.S.C. § 112

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. The Examiner contends that there is insufficient antecedent basis for this limitation in the claim. Applicants suggest that the claim as filed particularly defines the claimed subject matter. However, in the interest of facilitating the prosecution of the application, Applicants have amended claim 6 to recite “a slidable valve.”

Applicants suggest that in view of the teaching of the specification, and the knowledge available to one of ordinary skill in the art, that claim 6 as amended defines the claimed subject matter with both clarity and particularity. In view of the above amendments and remarks, Applicants respectfully request the withdrawal of the rejection of claim 6 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 USC § 103

Claims 8, 10, 11 and 13 are rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 3,859,996 (hereinafter “Mizzy”) in view of U.S. Patent No. 6,264,637 (hereinafter “Hogan”). Applicants respectfully traverse these rejections. To establish a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claim limitations. Manual of Patent Examining Procedure § 2143.03, page 2100-133. Neither Mizzy nor Hogan, either alone or in combination, teach or suggest the needle-free injector device claimed in independent claim 8 or independent claim 13.

Claim 8 recites a needle-free injection device including a syringe assembly, a pressurized gas delivery mechanism configured to apply gas to the syringe assembly, and a marking assembly which is activated by exhaust gas. Claim 8 is presented below for the Examiner’s convenience:

8. A needle-free injection device comprising:
 - a user-grippable housing;
 - a syringe assembly movably secured to the housing and configured to expel injectable fluid out of the nozzle upon application of a pressurized gas to the syringe assembly;
 - a pressurized gas delivery mechanism disposed within the housing and configured to selective apply pressurized gas to the syringe assembly; and
 - a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred, the marking assembly being fluidly coupled with the needle-free injection device, such that the marking device is activated by exhaust gas from the gas delivery mechanism.

Independent claim 13 also recites a needle-free injection device. As claimed, the needle-free injection device of claim 13 includes a gas reservoir, a syringe assembly which expels injectable fluid upon activation of pressurized gas from the gas reservoir to the syringe assembly, a marking assembly, and an exhaust gas pathway which directs exhaust gas from the pressurized gas delivery mechanism to the marking assembly. Claim 13 is presented below:

13. A needle-free injection device, comprising;
 - a gas reservoir;
 - a syringe assembly configured to expel injectable fluid out of a nozzle upon application of pressurized gas from the gas reservoir to the syringe assembly;
 - a pressurized gas delivery mechanism adapted to apply pressurized gas to the syringe assembly;
 - a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred; and
 - an exhaust gas pathway configured to direct at least a portion of exhaust gas from the pressurized gas delivery mechanism to the marking assembly.

Both claim 8 and claim 13 recite the delivery of exhaust gas to the marking assembly. As disclosed in the specification at page 19, lines 12-16, and page 22, lines 2-13, after an injection is delivered through the syringe assembly, exhaust gas is vented to the marking assembly and activates the marking assembly to make a mark. Importantly, the exhaust gas is pressurized gas which is vented from a reservoir after the syringe assembly is fired to deliver the injection.

Applicants agree with the Examiner that Mizzy discloses a needle-free injector including a syringe assembly and a pressurized gas delivery mechanism, and that Hogan discloses a needle injector coupled with a marking device. However, not only do Mizzy and Hogan fail to disclose the needle-free injection device of claims 8 and 13, which include a marking assembly capable of making a mark via exhaust gas after an injection is delivered, Hogan actually teaches away from such a device.

Hogan specifically teaches an injector device configured to simultaneously deliver an injection and a marking. The needle injector of Hogan includes a vaccine dosage syringe and an ink dispenser coupled by a common handle. As described at col. 4, lines 34-52, the Hogan injector acts to simultaneously inject a vaccine dose and dispense an ink marking.

While the preferred embodiment of Hogan simultaneously delivers vaccine and ink through manual activation of a common handle, at col. 6, lines 40- 57, Hogan briefly discloses an alternative embodiment in which the common handle is activated by pressurized gas. In such an

embodiment utilizing pressurized gas “the source of compressed gas discharges an amount of gas sufficient to advance both the ink syringe plunger 80 and the plunger 60 within the ink dosage chamber 81 and the dosage chamber 61 so as to discharge chamber contents...” Col. 6, lines 46-50. Thus, compressed gas is delivered simultaneously to the vaccine dosage chamber and the ink chamber to simultaneously deliver a vaccine and an ink marking.

The combination of Mizzy and Hogan fails to teach the injection device of claims 8 and 13 which delivers a marking via exhaust gas after an injection is delivered. Mizzy entirely lacks any marking assembly, and Hogan fails to add to the Mizzy disclosure with respect to these recited elements. For at least this reason, Applicants respectfully submit that claims 8 and 13 are not obvious over Mizzy in view of Hogan. Accordingly, Applicants request withdrawal of the rejections of claims 8 and 13, and dependent claims 10 and 11.

Double Patenting Rejections

Claims 1, 2, 8-10 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of U.S. Patent No. 6,676,630 (hereinafter ‘630). Claims 3, 4 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of ‘630 in view of Hogan. Applicants suggest that the prior generic coverage of newly presented claims does not, in and of itself, result in the obviousness of subsequently presented claims having differing scope and content. However, in the interest of facilitating the allowance of the instant application, applicants hereby submits a terminal disclaimer over ‘630 with the appropriate fee for a statutory disclaimer (enclosed).

Claim 13 has been amended to correct a typographical error only.

It is believed that the subject patent application has been placed in condition for allowance, and such action is respectfully requested. If the Examiner has any questions or concerns, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.

CERTIFICATE OF MAILING

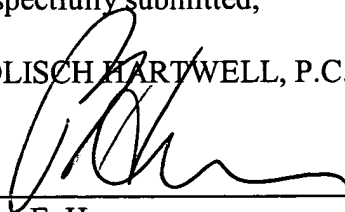
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on January 18, 2006.



Suzanne Lukas-Werner

Respectfully submitted,

KOLISCH HARTWELL, P.C.



Peter E. Heuser
Registration No. 27,902
Customer No. 23581
Attorney for Applicant
520 S.W. Yamhill Street, Suite 200
Portland, Oregon 97204
Telephone: (503) 224-6655
Facsimile: (503) 295-6679